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Computer-based treatment to reduce slowing of movement and fatigue in Parkinson's disease

Submission date
16/01/2018

Registration date
04/04/2018

Last Edited
04/01/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

✓ Retrospectively registered

✓ Protocol added

? SAP not yet added

? Results not yet added and study completed for more than 2 years

? Raw data not yet added

✓ Study completed

Plain English Summary

Background and study aims
Parkinson’s disease (PD) is a long-term medical condition that affects over 120,000 people in the UK, and about 5 million people worldwide. PD is caused by the loss of cells in an area of the brain called the substantia nigra, which create the chemical messenger (neurotransmitter) dopamine. Over time, more cells in this region gradually die, less dopamine is produced, and movements become less coordinated and more difficult to perform. People with PD may show signs of abnormal movements, such as stiffness, tremor (uncontrollable shaking) and slowness of movement (bradykinesia), and often tire easily. These symptoms get gradually worse over time. People with PD are commonly given medications to increase the amount of dopamine in the brain but long-term use can cause a number of side effects. Complimentary treatments carried out alongside drug treatment can help to maintain function and improve quality of life. The aim of this study is to test the effectiveness of a computer-based task for improving/maintaining movement performance and fatigue in people with PD. The aim is to get feedback on the tasks for future development of the treatment.

Who can participate?
Patients with early stage PD in the North Wales area

What does the study involve?
Participants meet with a researcher in their own homes, at the movement disorders clinic, or at Bangor University. The researcher organises to visit participants up to five times after the first session. The time between sessions is flexible and works around the participants. Participants are randomly allocated to one of two groups. One group completes a task involving mentally tracking the position of a target moving around a grid. The other group completes one of two tasks that are appear to be identical but do not require imagined sequential tracking of an object through space. The effects of the tasks are compared to see which is the most effective. There are also measurements of how fluid and fast the participants move plus a series of questionnaires. The study also explores whether the outcomes are related to other measures, like quality of life, fatigue and non-motor symptoms.

What are the possible benefits and risks for participating?
The results of the study will be used to inform the development of a larger study that will target many more patients with PD. Participants may find the study beneficial and interesting, and find it enjoyable to complete the tasks and questionnaires and to talk with the researcher. There are no notable risks involved with participating.

Where is the study run from?
School of Psychology, Bangor University and BCUHB Movement Disorders Clinic, Llandudno General Hospital (UK). Testing can take place at either of these sites or in the participant's own home.

When is study starting and how long is it expected to run for?
September 2017 to August 2018

Who is funding the study?
Betsi Cadwaladr University Health Board (UK)

Who is the main contact?
Prof. Charles Leek

Contact information

Type(s)
Scientific

Contact name
Mr Joshua Payne

ORCID ID
http://orcid.org/0000-0002-4372-9307

Contact details
School of Psychology
Bangor University
Bangor, Gwynedd
United Kingdom
LL57 2AS
+44 (0)1248 382925
psp0a1@bangor.ac.uk

Type(s)
Scientific

Contact name
Prof Charles Leek

Contact details
School of Psychology
Bangor University

Bangor, Gwynedd
United Kingdom
LL57 2AS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
NHSREC232195/BU2017-16109

Study information

Scientific Title
Early stage feasibility assessment of a non-pharmacological intervention for motor slowing and fatigue in Parkinson's disease

Study hypothesis
1. Clinically significant gains of >= 5 points relative to baseline on the motor examination of the UPDRS following a visuospatial intervention compared to number subtraction control intervention.
2. Improvements in secondary measures of movement kinematics (onset-delay time and velocity), quality of life (PDQ-8) and motor fatigue (finger tapping, PFS-16) in the intervention group over and above the control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. North Wales NHS REC, Project ID: 232195
2. School of Psychology, Bangor University REC, 27/09/2017, ref: 2017-16109
3. NHS IRAS, 07/11/2017
4. NHS R&D, 05/01/2018

Study design
Single-centre randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Condition
Parkinson's disease

Interventions
Participants will be randomly assigned to take part in the intervention or control arm of the study. Allocation order was generated by sorting over set of randomly generated integers, following generation of anonymised participant numbers with idGenerator software (Olden et al., 2016). The intervention task is a Sequential Grid Navigation task (visuospatial task) that involves mentally tracking the position of a target moving around a grid. The control group will complete one of two tasks over the intervention period: a sequential subtraction task or a spatial memory task, that are identical in visual features but crucially do not require imagined sequential tracking of an object through space. In the initial session, the trialists will seek informed consent from participants. Providing participants attained a score of 24 and above on the MoCA, the rest of the initial session will continue with completion of several background questionnaires on demographics, non-motor symptoms (NMS), fatigue (PFS-16), sleep (PDSS) and quality of life (PDQ-8). Participants in both groups will then complete five intervention sessions in their own homes, in the clinic, or at the School of Psychology, at their convenience with a minimum frequency of one session per week. The primary clinical outcome measure, the UPDRS, will be assessed at the beginning of session one and the end of session five, and video recorded for secondary blind ratings by a trained clinician. Secondary measures of 60 second finger tapping (30s each hand) and a computerised kinematic reaching task will be conducted before and after the delivery of each intervention or control task, in each of the five sessions. Participants will debriefed in the final session, where they will be asked to feedback on the study protocol.

Intervention Type
Behavioural

Primary outcome measure
Clinically significant change of >= 5 in the motor score from the UPDRS from session 1 to session 5

Secondary outcome measures
1. Computerised movement kinematics tasks that measure accuracy and response times, measured using a touchscreen computer in each testing session
2. Finger tapping frequency over a 30s period as a secondary measure of motor fatigue, collected for both hands in each testing session

Overall study start date
01/09/2017

Overall study end date
31/08/2018

Eligibility

Participant inclusion criteria
1. A diagnosis of Parkinson's Disease according to UK Brain bank Diagnostic Criteria confirmed by a specialist
2. Hoehn and Yahr Stage 1-3
3. Ability to give informed consent as assessed by a specialist
Clinical determination based on the inclusion and exclusion criteria will be assessed by Dr John Hindle

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40-60

Participant exclusion criteria
1. A clinical diagnosis of dementia
2. History of other significant neurological conditions
3. The presence of visual hallucinations
4. Cognitive impairment - MoCA score of less than 24
5. Significant visual impairment affecting ability to view computer screen

Recruitment start date
01/11/2017

Recruitment end date
30/07/2018

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
School of Psychology, Bangor University
Brigantia Building
Penrallt Road

Bangor, Gwynedd
United Kingdom
LL57 2AS

Study participating centre
BCUHB Movement Disorders Clinics
Lladudno General Hospital
Hospital Road
Llandudno
United Kingdom
LL30 1LB

Sponsor information

Organisation
Bangor University

Sponsor details
School of Psychology
Penrallt Road
Bangor, Gwynedd
Wales
United Kingdom
LL57 2AS

Sponsor type
University/education

ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
University/education

Funder Name
Betsi Cadwaladr University Health Board Pathway to Portfolio

Results and Publications

Publication and dissemination plan

The trialists plan to publish the study protocol with statistical analysis plan in the near future. Additional documents, such as participant consent forms and extended protocol may also be made available. Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date

01/09/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be made available upon request from Prof. Charles Leek. All deidentified participant-level datasets pertinent to the study, along with relevant analysis scripts, will be made available following article publication to achieve the aims of a methodologically sound proposal or for use in meta-analysis.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/12/2018		Yes	No